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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/867,693	05/31/2001	Mark J. Cooper	003659.00009	6189

22907 7590 10/02/2002

BANNER & WITCOFF  
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WASHINGTON, DC 20001

EXAMINER
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NGUYEN, DAVE TRONG

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 10/02/2002 10

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/867,693

Applicant(s)

COOPER ET AL.

Examiner

Dave Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM  
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-186 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-186 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_. 6) ☒ Other: *detailed action*.

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Claims 177-186 have been added by the preliminary amendment filed August 9, 2002.

***Election/Restriction***

In view of an enormous number of claims (186 claims) being filed, which embraces multiple distinct claimed inventions, Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claim 1, and claims dependent there from, drawn to a method of estimating the colloidal stability of a preparation of compacted nucleic acids, classifiable in class 435, subclass 6.

Group II. Claims 2, 20, 29, 32, 35, 47-58, 103, 116, 131, 139, 147, 154, 164, and claims dependent there from, drawn to a composition comprising unaggregated nucleic acid complex(s), the complex consisting essentially of a single nucleic acid molecule and one or more polycation molecules, said polycation molecules having a counter ion selected from the group consisting of acetate, bicarbonate, and chloride, and a method of employing the composition to deliver the nucleic acid molecule to a cell, classifiable in class 435, subclass 320.1, class 435, subclass 455.

Group III. Claims 10, 38, 160, and claims dependent there from, drawn to a method of employing an effective amount of salt concentration to prepare a composition comprising unaggregated nucleic acid complex(s), the complex consisting essentially of a single nucleic acid molecule and one or more polycation molecules, said polycation molecules having a counter ion selected from the group consisting of acetate, bicarbonate, and chloride, classifiable in class 435, subclass 91.4.

Group IV. Claims 41, 44, and claims dependent there from, drawn to a method of employing an effective amount of a solvent absent of salt to prepare a composition comprising unaggregated nucleic acid complex(s), the complex consisting essentially of a single nucleic acid molecule and one or more polycation molecules, said polycation molecules having a counter ion selected from the group consisting of

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acetate, bicarbonate, and chloride, classifiable in class 435, subclass 91.4.

Group V. Claims 59-68, drawn to a method of preventing or treating any disease or clinical condition in a subject, classifiable in class 514, subclass 44.

In view of an enormous number of dependent claims present randomly in this application, which is already an undue burden of the examiner to prepare this restriction requirement, a reply to this restriction requirement the must also identify the claims readable on the elected invention and/or species, including any claims subsequently added.

The inventions are distinct, each from the other because of the following reasons:

Group I, Group II, Group III, Group IV, and Group IV are distinct because the methods of Groups I, II, III, and IV are directed to distinct goal, materially distinct steps, and generates distinct functions and effects. In addition, the composition of Group II is not limited to any particular preparation process, as evidenced by distinct processes of preparation as claimed in Group II and III, respectively. As a result, a search for prior art and consideration of patentability of all claims does not necessarily overlap with one another, thereby generating an undue burden on the examiner.

Should any of the above Group be elected, the claims of the elected Group are generic to a plurality of disclosed patentably distinct species comprising:

A/ A specifically named counter ion: acetate, bicarbonate and Chloride.

B/ A specifically named species of polycation: see claims 21, 22, 105, 118, 132, 140, 148, 155, 172, 177-183.

C/ A specifically named species of diameter: see claims 25-28, for example.

D/ A specifically named species of monitored assay: see claim 17, for example.

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed named species from A/, B/, C/ and C/ even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, fall into different statutory classes of invention, and are separately classified and searched, and/or because of the patentably distinct species as listed above (the listed species, as evidenced by each of the respective and art recognized named molecule, are structurally distinct), it would be unduly burdensome for the examiner to search and examine all of the subject matter being sought in the presently pending claims, and thus, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications regarding the formalities should be directed to Patent Analyst Dianiece Jacobs, whose telephone number is **(703) 305-3388**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Reynolds*, may be reached at **(703) 305-4051**.

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Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is **(703) 305-7401**.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Trong Nguyen  
Primary Examiner  
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**DAVE T. NGUYEN  
PRIMARY EXAMINER**